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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,235	11/06/2001	Seth Lederman		5392
61544 7590 11/02/2009 KAREN GUERRERO			EXAMINER	
25 ROOSTER	HILL RD		ROYDS, LESLIE A	
PHOENIXVILLE, PA 19460			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			11/02/2009	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
09/992,235	LEDERMAN ET AL.	
Examiner	Art Unit	
Leslie A. Royds	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.
1. 🛮 The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of th
application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the
application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request
for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time
periods:

The period for reply expires \_\_\_ months from the mailing date of the final rejection.

b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO

MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### NOTICE OF APPEAL

The Notice of Appeal was filed on \_ . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

### AMENDMENTS

3. X The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) They raise new issues that would require further consideration and/or search (see NOTE below);
(b) They raise the issue of new matter (see NOTE below):
(c) 🛮 They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for
appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).
4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. Applicant's reply has overcome the following rejection(s):
6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the
non-allowable claim(s).
7. 🔀 For purposes of appeal, the proposed amendment(s): a) 🔯 will not be entered, or b) 🔲 will be entered and an explanation of
how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed:
Claim(s) objected to: 33 and 35.
Claim(s) rejected: 1-8 and 30-35.
Claim(s) withdrawn from consideration: 25-27.
AFFIDAVIT OR OTHER EVIDENCE
2 The efficient or other authorized filed ofter a final action, but before or on the date of filing a Nation of Annual will not be entered

- because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

- 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- Note the attached Information Disclosure Statement(s), (PTO/SB/08) Paper No(s).

13. Other: \_\_

/Ardin Marschel/ Supervisory Patent Examiner, Art Unit 1614

/Leslie A. Royds/ Patent Examiner, Art Unit 1614

#### Continuation of 3 NOTE:

Applicant's proposed after-final amendment filed October 15, 2009 will not be entered into the record because the proposed amendment raises new issues that would require further consideration and/or search. Specifically, Applicant has failed to the listing of the claims by omitting instant claim 28 from the claim listing submitted October 15, 2009. This clearly would require additional consideration after-final were the proposed amendment to be entered into the record. Accordingly, the proposed amendment will not be entered, in addition, the proposed claim amendments are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal because they raise new issues that require further consideration and/or search as described above.

Continuation of 11, does NOT place the application in condition for allowance because:

Applicant's request for reconsideration of the present application with regard to the objections and/or rejections of record in light of the amendments to the claims proposed and presented in the after-final amendment as been made. In light of the fact that the proposed amendments to the claims will not be entered into the record, Applicant's remarks directed to the obviation of these rejections as a result of the proposed amendments are not found persuasive.

Insofar as Applicant's remarks apply to the previously pending set of claims. Applicant traverses the written description rejection over claims 3a and 35, stating that the Figures a sociated with Figures 3. 4 and 7 implicitly support the concept that Applicant's envisioned using the claimed compound at a dosage of "about 1 mg/kg" as claimed rather than simply a dosage of 1 mg/kg. This is unpersuasive because it is clear from the accompanying description of the Figures present that the only dosage amount scontemplated and employed by Applicants were 0.1, 1 and 10 mg/kg, not doses "around" or "about" each of those values. Though it is agreed that the Figures present the data as a continuous line graph, it is noted for the record that this is an attempt to extrapolate the results beyond those data points actually conceived of and tested (i.e., 0.1, 1 and 10 mg/kg) and does not either explicitly or implicitly demonstrate that Applicant contemplated or conceived of a composition of the claimed compound that was capable of achieving this unexpected result at any other dosage amounts other than those explicitly described (i.e. in the case of instant claims 33 and 35, for a dose of 1 mg/kg.)

For these reasons, the claims remain rejected for the reasons previously set forth in the final rejection dated September 21, 2009.

/Leslie A. Royds/ Patent Examiner, Art Unit 1614